



## URGENT DEVICE RECALL NOTICE

Zimmer Dental

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To: U.S. Dentists and Health Care Professionals

**Affected Product:** Tool, Driver, Hex, 2.5mm x 28mm

Catalog RHL2.5

Etched Lot Numbers: 62699693 & 62735177

Catalog Number	Lot Number on Label	Etched Lot Number of RHL2.5
RHL25	62712431	62699693
RHL25	62743168	62735177
OPCST	62766610	62735177
TSVKIT	62702589	62699693
TSVKIT	62710484	62699693
TSVKIT	62712437	62699693
TSVKIT	62743075	62735177
TSVKIT	62750487	62735177
TSVKIT	62753787	62735177
TSVKIT	62756920	62735177
TSVKIT	62759862	62735177
TSVKIT	62760388	62735177
TSVKIT	62768456	62735177
TSVKIT	62773158	62735177

Dear Health Care Professional:

Zimmer Dental is conducting a voluntary recall of the above products. Our records indicate that your office previously received a shipment of the affected lot(s) between May-October 2014.

Through investigation, Zimmer Dental determined that certain lots of the *GemLock*® Long Hex Driver, Catalog RHL2.5, (the "Affected Product") may not fit into the Fixture Mount Transfer (FMT) or the internal hex of the implant. The Affected Product was also distributed within the *Tapered SwissPlus* & *SwissPlus* Implant Systems Kit, Surgical, Complete, Catalog OPCST as well as the *Tapered Screw-Vent* Implant System Surgical Kit, Complete, Catalog TSVKIT, so please search all of your kits. The Affected Product is easily identifiable regardless of the lot number on the label, as the Affected Product is etched with one of the following supplier lot numbers: 62699693 & 62735177. Nevertheless, please reference the above table for a listing of all lot numbers.



## URGENT: DEVICE RECALL NOTICE

Tool, Driver, Hex, 2.5mm x 28mm  
P/N RHL2.5, Lots 62712431 & 62743168

### Risks:

- If the clinician attempts to use *GemLock* Long Hex Driver and the driver does not fit into the internal hex of the FMT, this could delay treatment while the surgeon obtains the *GemLock* Hex Short Driver (RH2.5) or *GemLock* Hex Drill Driver (RHD2.5) from the Instrument Kit to continue placement.
- If the clinician attempts to use the *GemLock* Long Hex Driver and the driver engages into the FMT but not the implant, this could delay treatment while the surgeon obtains the *GemLock* Hex Short Driver (RH2.5) or *GemLock* Hex Drill Driver (RHD2.5) from the Instrument Kit to continue placement.

### Responsibilities:

1. Please review this notice and check your inventory for the affected units.
2. Immediately quarantine and remove all affected products from service.
3. If you have product to return, please **call Zimmer Dental Customer Service at 1-800-854-7019** to obtain a Return Authorization Number and to setup a FedEx pick-up to return the products.
4. Complete the attached Business Reply Form and fax it to 574-372-4265 or email to [corporatequality.postmarket@zimmer.com](mailto:corporatequality.postmarket@zimmer.com).
5. Return affected product to Zimmer Dental along with the return authorization number.

Please maintain a copy of this notice and a signed copy of Attachment 1 for your records to assist in any future regulatory agencies audits of this field action.

### Other Information

This voluntary notification will be reported to the U.S. Food and Drug Administration.

Under 21 CFR Part 803, manufacturers are also required to report any serious injuries where a device has contributed to or may have contributed to the event. Please keep Zimmer informed of any adverse events associated with this device or any other Zimmer product. Adverse events may be reported to Zimmer at [Dental.USorders@zimmer.com](mailto:Dental.USorders@zimmer.com).

**MedWatch Reporting:** Adverse reactions or quality problems experienced with the use of this product may be reported to the FDA's MedWatch Adverse Event Reporting program either online, by regular mail or by fax.

- Online: [www.fda.gov/medwatch/report.htm](http://www.fda.gov/medwatch/report.htm)
- Regular Mail: use postage-paid, pre-addressed Form FDA 3500 available at: [www.fda.gov/MedWatch/getform.htm](http://www.fda.gov/MedWatch/getform.htm). Mail to address on the pre-addressed form.
- Fax: 1-800-FDA-0178

Zimmer Dental takes quality very seriously, and we work diligently to ensure that we are improving lives by developing and delivering high quality, safe and effective products. We apologize for any inconvenience this may have caused and appreciate your continued business. For assistance or any other questions that you may have, please contact Zimmer Dental Customer Service at 1-800-854-7019. Customer Service is available 7:00am to 5:00pm (Pacific), Monday through Friday.